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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 325,963	06 04 1999	BONNIE WEISKOPF ALBRECHT	54664USA4A	3500

7590

03 27 2002

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EXAMINER

ROCHE, LEANNA M

ART UNIT

PAPER NUMBER

1771

35

DATE MAILED: 03 27 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,963

Applicant(s)

ALBRECHT ET AL.

Examiner

Leanna Roche

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 25-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 13, 15, 16, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Walther (USPN 5905097).

Walther is directed to the production of breathable foams comprised of styrene-butadiene block copolymers (Example 5). This reads on Applicant's specific thermoplastic, amorphous polymer and Applicant's foam layer comprised of a pressure sensitive adhesive polymer. The foams of Walther are produced as sheets, and therefore, inherently have a major longitudinal surface. Because pores are three-dimensional, they are inherently perpendicular to at least one side of the sheet of foam in which they are a part. Walther discloses thicknesses between about 76 and about

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305 microns (Example 4 Table) which are within Applicant's presently claimed range.

Walther discloses depositing the breathable foam onto a metal surface. This reads on an article having at least two layers, one of the layers being non-porous.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 13-17, 25-27, 29, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volke (USPN 4743499) in view of Cilento et al. (USPN 4427737).

The teachings of Volke are substantially as set forth in Paper No. 7, pages 3-5. However, Volke does not specifically disclose a breathable foam layer having a thickness of about 86 to 265 microns. Cilento discloses a breathable tape for use in various medical or health care purposes comprised of a porous backing layer and a microporous adhesive layer. The porous backing layer of Cilento may be polyurethane foam having a thickness from about 76.2 to 508 microns (Column 1, lines 32-47). It is known in the art that by decreasing the thickness of a foam sheet the overall flexibility of that foamed sheet will increase. Therefore, it would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of Cilento and Volke, motivated by the desire to produce a wound dressing with increased flexibility.

With regard to amended claim 17, because the foam layer of Volke is flexible, it is inherently capable of stretching. Stretching is known to increase the size of pores in a porous material. Increased pore size inherently causes an increase in the amount of

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moisture vapor that can pass through each pore. An increased amount of moisture vapor passage results in an increased moisture vapor transition rate. Therefore, the flexible foam layer of Volke would inherently display an increased moisture vapor transition rate upon stretching.

With regard to Claim 34, Volke discloses a foam layer of polyurethane. This reads on Applicant's foam layer comprising a pressure sensitive adhesive polymer.

5. Claims 13-17, 25-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (USPN 3972328) in view of Cilento et al. (USPN 4427737).

With regard to claims 13-17 and 25-28, the teachings of Chen are substantially as set forth in Paper No. 7, pages 5-6. However, Chen does not specifically disclose a breathable foam layer having a thickness of about 86 to 265 microns. Cilento discloses a breathable tape for use in various medical or health care purposes comprised of a porous backing layer and a microporous adhesive layer. The porous backing layer of Cilento may be polyurethane foam having a thickness from about 76.2 to 508 microns (Column 1, lines 32-47). It is known in the art that by decreasing the thickness of a foam sheet the overall flexibility of that foamed sheet will increase. Therefore, it would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of Cilento and Chen, motivated by the desire to produce a surgical bandage with increased flexibility.

With regard to amended claim 17, because the foam layer of Chen is flexible, it is inherently capable of stretching. Stretching is known to increase the size of pores in a porous material. Increased pore size inherently causes an increase in the amount of

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moisture vapor that can pass through each pore. An increased amount of moisture vapor passage results in an increased moisture vapor transition rate. Therefore, the flexible foam layer of Chen would inherently display an increased moisture vapor transition rate upon stretching.

With regard to claims 34 and 35, Chen discloses a breathable foam layer comprising styrene-butadiene foams. This reads on Applicant's foam layer comprising a pressure sensitive adhesive polymer, and Applicant's thermoplastic, amorphous polymer consisting of a styrene-butadiene-styrene block copolymer.

6. Claims 13-17, 25-27, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bello et al. (USPN 5716621) in view of Cilento et al. (USPN 4427737).

The teachings of Bello are substantially as set forth in Paper No. 7, pages 6-7. However, Bello does not specifically disclose a breathable foam layer having a thickness of about 86 to 265 microns. Cilento discloses a breathable tape for use in various medical or health care purposes comprised of a porous backing layer and a microporous adhesive layer. The porous backing layer of Cilento may be polyurethane foam having a thickness from about 76.2 to 508 microns (Column 1, lines 32-47). It is known in the art that by decreasing the thickness of a foam sheet the overall flexibility of that foamed sheet will increase. Therefore, it would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of Cilento and Bello, motivated by the desire to produce a drug delivery dressing with increased flexibility.

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With regard to amended claim 17, because the foam layer of Bello is flexible, it is inherently capable of stretching. Stretching is known to increase the size of pores in a porous material. Increased pore size inherently causes an increase in the amount of moisture vapor that can pass through each pore. An increased amount of moisture vapor passage results in an increased moisture vapor transition rate. Therefore, the flexible foam layer of Bello would inherently display an increased moisture vapor transition rate upon stretching.

With regard to Claim 34, Bello discloses a foam layer of polyurethane. This reads on Applicant's foam layer comprising a pressure sensitive adhesive polymer.

7. Claims 13, 14, 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenneco Chemicals, Inc. (GB 1321489) in view of Cilento et al. (USPN 4427737).

The teachings of Tenneco are substantially as set forth in Paper No. 7, pages 8-9. However, Tenneco does not specifically disclose a breathable foam layer having a thickness of about 86 to 265 microns. Cilento discloses a breathable tape for use in various medical or health care purposes comprised of a porous backing layer and a microporous adhesive layer. The porous backing layer of Cilento may be polyurethane foam having a thickness from about 76.2 to 508 microns (Column 1, lines 32-47). It is known in the art that by decreasing the thickness of a foam sheet the overall flexibility of that foamed sheet will increase. Therefore, it would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of Cilento and

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Tenneco, motivated by the desire to produce a foamed cellular sheet with increased flexibility.

With regard to amended claim 17, because the foam layer of Tenneco is flexible, it is inherently capable of stretching. Stretching is known to increase the size of pores in a porous material. Increased pore size inherently causes an increase in the amount of moisture vapor that can pass through each pore. An increased amount of moisture vapor passage results in an increased moisture vapor transition rate. Therefore, the flexible foam layer of Tenneco would inherently display an increased moisture vapor transition rate upon stretching.

With regard to Claim 34, Tenneco discloses a foam layer of polyurethane. This reads on Applicant's foam layer comprising a pressure sensitive adhesive polymer.

8. Claims 28, 30, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volke (USPN 4743499) in view of Cilento et al. (4427737) as applied to claims 13, 25 and 29 above, and further in view of Chen (USPN 3972328).

With regard to Claims 28 and 30, Volke discloses a flexible, open-cell amorphous, thermoplastic foam core, but does not disclose a foam layer comprised of a thermoplastic elastomer. Chen, however, is directed to a surgical bandage whose foam core may be comprised of a semi-open cell styrene-butadiene foam which is an amorphous, thermoplastic elastomer. Elastomers display increased elasticity, and therefore have increased cushioning capabilities. It would have been obvious to the skilled artisan at the time the invention was made to combine the teachings of Voike

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and Chen, motivated by the desire to produce a bandage with a foam core which displays increased cushioning properties.

With regard to Claim 31, neither Volke nor Chen specifically disclose the moisture vapor transmission rate of the polymeric film/foam article. However, Chen does disclose that the polymeric film be somewhat gas permeable. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the moisture vapor transmission rate of the film/foam article, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233). In the present case, it would have been obvious to optimize the moisture vapor transmission rate, motivated by the desire to aid in the passage of air to the surface of the skin which is covered by the disclosed bandage.

With regard to Claim 35, Volke does not specifically disclose the use of a thermoplastic, amorphous polymer from Applicant's list. Chen, however, discloses the use of a semi-open cell styrene-butadiene foam which is an amorphous, thermoplastic elastomer. Elastomers display increased elasticity, and therefore have increased cushioning capabilities. It would have been obvious to the skilled artisan at the time the invention was made to combine the teachings of Volke and Chen, motivated by the desire to produce a bandage with a foam core which displays increased cushioning properties.

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Response to Arguments

9. Applicant's arguments with respect to claims 13-17 and 25-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

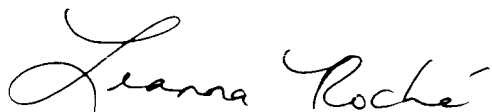
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leanna Roche whose telephone number is 703-308-

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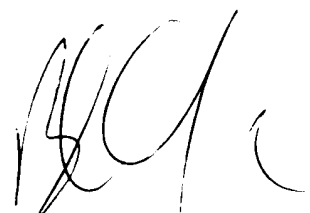
6549. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm (with alternate Mondays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 703-308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Imr
March 21, 2002



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